K010597

MAY 2 9 2001

Summary of Safety & Effectiveness
SYNCHRON® LX Systems
High Sensitivity C-Reactive Protein (CRPH) Reagent

1.0 **Submitted By:**

Annette Hellie
Principal Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 993-8767
FAX: (714) 961-4123

2.0 **Date Submitted:**

February 27, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON LX® Systems High Sensitivity C-Reactive Protein (CRPH) Reagent

3.2 **Classification Name**
C-Reactive Protein immunological test system (21 CFR § 866.5270)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
LX Systems CRPH Reagent	Dade Behring N High Sensitivity CRP	Dade Behring Inc.*	K991385

*Dade Behring Inc. (Newark, DE)

5.0 **Description:**

The SYNCHRON LX® Systems CRPH reagent, when used in conjunction with Beckman Coulter SYNCHRON LX® PRO Systems and SYNCHRON CAL 5 Plus, is intended for use in the quantitative determination of human C-reactive protein in human serum and plasma samples by rate turbidimetry.

6.0 **Intended Use:**

High Sensitivity CRPH reagent, when used in conjunction with Beckman Coulter SYNCHRON LX® PRO Systems and SYNCHRON CAL 5 Plus, is intended for use in the quantitative determination of human C-reactive protein in human serum and plasma samples by rate turbidimetry.

Clinical Significance:
Measurement of C-reactive protein aids in evaluation of stress, trauma, infection, inflammation, surgery, and associated diseases.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

	Similarities	
LX CRPH Reagent	Intended Use	Same as Dade Behring N High Sensitivity CRP
	Use of Latex particle technology	
	Liquid stable reagent	
	Differences	
LX CRPH Reagent	Antibody source	LX CRPH uses goat and mouse while the Dade Behring Kit uses mouse only.
	Initial dilution range	The LX initial dilution range covers from 0.02 to 6.0 mg/dL while the Dade Behring Kit covers from 0.30 to 22.0 mg/dL
	Extended dilution range	The LX extended dilution range covers up to 144.0 mg/dL while the Dade Behring Kit covers up to 110.0 mg/dL

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, linearity, and imprecision experiments.

Method Comparison Study Results

Analyte	Slope	Intercept	r	n	Predicate Method
LX PRO CRPH Reagent	1.011	-0.036	0.994	141	Behring N High Sensitivity CRP

LX PRO System CRPH Estimated Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	0.070	0.0027	3.9	80
Level 2	1.53	0.0197	1.3	80
Level 3	4.25	0.0688	1.6	80
Level 4	7.75	0.1179	1.5	80
Total Imprecision				
Level 1	0.070	0.0036	5.1	80
Level 2	1.53	0.0618	4.1	80
Level 3	4.25	0.1749	4.1	80
Level 4	7.75	0.2640	3.4	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 9 2001

Ms. Annette Hellie
Principal Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
M/S W-104
Brea, CA 92822-8000

Re: 510(k) Number: K010597
Trade/Device Name: Synchron® LX Systems High Sensitivity C-Reactive Protein (CRPH) Reagent
Regulation Number: 866.5270
Regulatory Class: II
Product Code: DCK
Dated: February 27, 2001
Received: February 28, 2001

Dear Ms. Hellie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010597

Device Name: **SYNCHRON® LX Systems**
High Sensitivity C-Reactive Protein (CRPH) Reagent

Indications for Use:

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Clinical Significance:

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Fred Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010597

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96